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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/848,159 05/03/01 YUAN **EXAMINER** HM12/1002 FRANK J. UXA ARTUNUI, S PAPER NUMBER STOUT, UXA, BUYAN & MULLINS, LLP SUITE 300 4 VENTURE DATE MAILEDL 7 IRVINE CA 92618

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

		Application No.	Applicant(s)
· /		09/848,159	YUAN ET AL.
	Office Action Summary	Examiner	Art Unit
		San-ming Hui	1617
Period fo	The MAILING DATE of this communication apports. Or Reply	pears on the cover sheet with	the correspondence address
THE - Exte after - If the - If NC - Failu - Any	ORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. a period for reply specified above is less than thirty (30) days, a repl or period for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a repl by within the statutory minimum of thirty (will apply and will expire SIX (6) MONTH e, cause the application to become ABAN	y be timely filed 30) days will be considered timely. IS from the mailing date of this communication. IDONED (35 U.S.C. § 133).
1)⊠	Responsive to communication(s) filed on 04	September 2001 .	
2a)□	This action is FINAL . 2b)⊠ Th	nis action is non-final.	
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposit	ion of Claims		
4)🛛	☑ Claim(s) <u>1-26</u> is/are pending in the application.		
	4a) Of the above claim(s) <u>7-10,13-15 and 17-21</u> is/are withdrawn from consideration.		
5)[Claim(s) is/are allowed.		
6)⊠	☑ Claim(s) <u>1-6, 11, 12, 16, and 22-26</u> is/are rejected.		
7)	Claim(s) is/are objected to.		
8)□	Claim(s) are subject to restriction and/o	or election requirement.	
Applicati	ion Papers		
9)[The specification is objected to by the Examine	er.	
10)	The drawing(s) filed on is/are: a)☐ acce	pted or b) objected to by the	Examiner.
	Applicant may not request that any objection to the	e drawing(s) be held in abeyand	ce. See 37 CFR 1.85(a).
11) 🗌	The proposed drawing correction filed on	_ is: a)∏ approved b)∏ disa	approved by the Examiner.
	If approved, corrected drawings are required in re	ply to this Office action.	
12)	The oath or declaration is objected to by the Ex	caminer.	
Priority ι	under 35 U.S.C. §§ 119 and 120		
13)	Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. §	119(a)-(d) or (f).
a)	☐ All b)☐ Some * c)☐ None of:		
	1. Certified copies of the priority document	s have been received.	
	2. Certified copies of the priority document	ts have been received in App	olication No
* 5	Copies of the certified copies of the prio application from the International Buse the attached detailed Office action for a list.	reau (PCT Rule 17.2(a)).	_
14) 🗌 A	14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
) The translation of the foreign language pro Acknowledgment is made of a claim for domest	• •	
Attachmen	t(s)	•	
2) 🔲 Notic	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s) _	5) Notice of Info	mmary (PTO-413) Paper No(s) ormal Patent Application (PTO-152)
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DETAILED ACTION

Applicant's election without traverse of species, AGN 194310 in Paper No. 3, received in September 4, 2001 is acknowledged.

Examiner appreciates applicants' pointing out that the claims 19-21 are also pending in the application. These claims were omitted by the examiner from the pending claims on the Form 326 mailed August 14, 2001 merely as an oversight.

Claims 1-26 are currently pending.

Claims 7-10, 13-15, and 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Claims 1-6, 11, 12, 16, and 22-26 have been examined herein to the extent they read on the elected species, AGN 194310.

Claim Objections

Claims 25 and 26 are objected to because of the following informalities: the use of parenthesis in claims 25 and 26, last line respectively: "(AGN 194310)", is considered improper. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The expression, "a method of preventing myocardial infarction" in claim 5, line 3, renders the claim indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Examples of how and when to prevent myocardial infarction are not set forth in the specification. Absent such exemplication, the skilled artisan could not establish the identity of those situations wherein <u>prevention</u> of myocardial infarction would be effected. Furthermore, it is unclear as to the degree of prevention (e.g., total prevention, some prevention, probable prevention, total prevention in most cases...etc.) herein because the specification does not disclose the extent of prevention achieved. Examiner would favorably consider the term "prophylaxis" over "prevention".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 11, 12, 16, 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (US Patent 5,776,699) in view of Aberg et al. (Atherosclerosis, 1985; 54:89-97).

Klein et al. teaches a group of RAR antagonists broadly, including the elected compound AGN 194310, being useful in inhibiting hypertriglyceride (See particularly Col. 3, line 45-col. 4, line 49; also col. 20, line 67).

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Klein et al. does not expressly teach the employment of AGN 194310 specifically in the method of lowering triglyceride. Klein et al. does not expressly teach the employment of AGN 194310 to prevent myocardial infarction.

Aberg et al. teaches that elevated serum triglyceride is one of the risk factor of developing myocardial infarction (See particularly page 89, third para.; also page 93, Table 1 and page 95, Table 3).

It would have been obvious to one skill in the art when the invention was made to employ AGN 194310 in a method to lower triglyceride level and prevent myocardial infarction.

One of ordinary skill in the art would have motivated to employ AGN 194310 in a method of lowering triglyceride level and preventing myocardial infarction because the RAR antagonists of Klein et al. are known to be useful in inhibiting hypertriglyceridemia. Therefore, employing any RAR antagonists of Klein et al., including AGN 194310, would have been reasonably expected to be useful in a method of lowering triglyceride level. Furthermore, it is known that elevated serum triglyceride increasees the risk of developing myocardial infarction in patients. Therefore, patients taking AGN 194310 to lower their serum triglycerides level would be reasonably expected to prevent the development of myocardial infarction.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-

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1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui September 27, 2001

> MINNA MOEZIE, J.D. SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600